REMARKS

I. Status of the Claims

Claims 1-11, 18-20 and 23-27 are pending in the application, and claims 10, 11 and 25 stand withdrawn. Thus, claims 1-9, 18-20, 23, 24, 26 and 27 are under consideration and stand rejected under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §103. The specific grounds for rejection are set out in detail below.

II. Objections

A. Amendment

The examiner has objected to the previous amendment as non-compliant given the use of an allegedly incorrect status identifier for claim 25. Since claim 25 was, in fact, amended, it is believed that the objection is not proper. However, in the interest of advancing the prosecution, a response to Notice of Non-Compliant Amendment has been filed prior to this response, thereby facilitating further amendment of the claims.

B. Declaration

The examiner has again objected to the oath & declaration. A new oath is provided herewith.

C. Specification

The first sentence containing priority information is objected to based on the status of U.S. Serial No. 10/778,915, which is now abandoned. An amendment is provided.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-9, 18-20, 23, 24, 26 and 27 are rejected as indefinite. It is argued that the recitation of serum half-life, even when drawn to use of an ELISA as the standard for measure, remains indefinite in light of alleged differences in assays, conditions and subjects. Applicants traverse the rejection, but in the interest of advancing the prosecution, the claim has been amended to drop reference to serum half-life, which in any event is an inherent property of the recited SEQ ID NOs. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

A. Written Description

Claims 1-9, 18-20, 23, 24, 26 and 27 are rejected as lacking an adequate written description. According to the examiner, the claims exceed the scope of written support in (a) reciting use of a diverse genus of human immunoglobulins that bind human EpCAM, and (b) encompassing treatment of malignant diseases not involving upregulated EpCAM expression. Again, applicants traverse, but in the interest of advancing the prosecution, the claims have been amended to address each of the issues presented above. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. New Matter

Claims 26 and 27, added in the previous response, are said to lack support in the specification. Applicants traverse, but in the interest of advancing the prosecution, the claims have been canceled without prejudice or disclaimer to pursuing the subject matter in one or more continuing applications. Reconsideration and withdrawal of the rejection is therefore requested.

C. **Enablement**

Claims 1-9, 18-20, 23, 24, 26 and 27 are rejected as lacking an enabling disclosure. In general, the issues set forth here are the same as those raised above with respect to written description. Therefore, it is believed that the previously discussed amendments address the enablement issues as well. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. **Rejection Under 35 U.S.C. §103**

Claims 1-9, 18-20, 23, 24, 26 and 27 are again rejected as obvious over Kufer *et al.* in view of Raum *et al.*, and Naundorf *et al.*, as evidenced by Oberneder *et al.*, Loh *et al.*, and Leyland-Jones. The examiner's detailed rebuttal of applicants' previous response, while appreciated, is seriously flawed from both legal and scientific standpoints. As such, applicants again traverse.

The first argument made by the examiner is that, in contrast to applicants' position, the prior art ***does*** suggest administration the MT201 antibody no more frequently than once very two weeks. The arguments in favor of this position are that (a) Kufer doesn't ***exclude*** such treatments, and hence ***encompass*** the claimed administration regimen, and (b) Kufer teaches that a murine antibody to EpCAM is administered once a month. Neither of these arguments, however, advances the rejection.

It is black letter law that a prior art teaching that merely encompasses later claimed subject matter is not anticipatory – a genus cannot anticipate a species. At least this much the examiner must agree to and the present claims are not rejected as anticipated. Nonetheless, the examiner ***seems*** to argue that the genus-species relationship of the prior art to the present claims

creates a presumption of obviousness. Such is not the case, and (not surprisingly) no case law is offered to support this conclusion. It remains incumbent upon the prior art (and the examiner) to provide each element of a valid *prima facie* case – a teaching of each element of the claimed invention, a motivation to modify the prior art to adopt the claimed elements, and a likelihood of success in so doing. *See In re Vaeck*, 20 USPQ.2d 1438 (Fed. Cir. 1991).

Turning to the question of ***murine*** antibodies to EpCAM, applicants remind the examiner that the present claims are limited to the sequences of a particular ***human*** antibody, MT201, and now further drawn to administration at intervals of 1-2 weeks. Does the examiner suggest that the properties of a mouse antibody are directly applicable to one from a human? No scientific evidence is offered in support of this conclusion. Indeed, the murine 17-A1 antibody (Panorex®) of Reithermüller (from reference C10, cited by the examiner), was provided in a quite different regimen – once every month. As is evident from FIG. 18, Example IV.4. of Kufer, MT201 (a.k.a. H79) shows much ***higher*** cytotoxic activity than Panorex®. Further, Raum discloses the beneficial properties of MT201, namely, a long *in vivo* half-life and minimal immunogenicity, and confirms the differences between MT201 and the 17-1A antibody of Riethmüller in cytotoxic activity (see page 146, right column second paragraph and Figure 5). Why then would one seek to ***increase*** the frequency of administration of MT201 over that of Panorex® when the former had a higher cytotoxic activity? The answer is that one would ***not*** make such a choice, but in fact would believe the opposite (less frequent administration) would be preferable. This line of reasoning is further supported by the accompanying Rule 132 declaration of one of the inventors, Dr. Nadja Prang.

The next point that the examiner advances is that "it would have been obvious to one ordinarily skilled in the art to have determined the most appropriate doses, schedules and routes

of administration for the antibody therapy ...." Assuming that to be true – and it is not contested that Loh and Leyland-Jones suggest the benefits of such an undertaking – the question still remains as to what that result might be. Moreover, it might turn out that there is ***no*** preferred dose, schedule or route to be found. By analogy, while it might be obvious to screen for a new drug to treat cancer, the identification of such a drug and its subsequent use in treating a patient could not be rendered obvious merely by the desirability of finding such. Indeed, it is a misnomer when one says that something "is within the skill of those in the art" in the context of obviousness. That phraseology is nowhere found in §103, but instead, is part of §112, first paragraph. Thus, what the skilled artisan might ***achieve*** is relevant to enablement, while obviousness requires satisfaction of each of the *Vaeck* factors set out above. Again, the attached declaration of Dr. Prang supports this view.

Turning to the particular cases cited in support of the rejection, the citation from the *Boesch* case, which actually derives from *In re Antonie*, 195 USPQ 6, (CCPA 1967), is not helpful. Taken to its logical conclusion, if dosing regimens are "result effective variables," then no dosing regimen would ***ever*** be patentable. Indeed, the facts of the *Boesch* case are extreme, where the claimed compositions recited ranges of metals were almost coextensive with those taught in the prior art, and in some cases actually ***broader*** than those taught in the prior art. This is hardly the fact pattern presented here. The facts of *Peterson* are similar to those of *Boesch*, with overlapping ranges of metals in the prior art and the claimed invention. Again, this case is inapplicable to the facts of the present application.

The final argument, if it can be termed that, is that dosing regimens are expected to vary from patient to patient, and that clinical trials are designed to determine such parameters. Applicants response to this is that, while possibly true, it is irrelevant to the question of

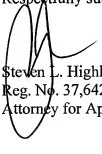
obviousness. And whether or not the PTO has facilities to make such assessment is similarly off the mark. The only question is whether the prior art suggests each element of the present claims, and despite the examiner's claims, the prior art fails.

In sum, the claims as presented for reconsideration describe methodologic aspects of cancer therapy that are neither taught nor suggested by the cited art. Similarly, it does not matter how desirable the ***finding*** of such parameters might be. As long as the prior art has not achieved this goal, no *prima facie* case exists. Reconsideration and withdrawal of the rejection is therefore requested.

VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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